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| 09/724,304      | 11/28/2000  | Yi-Ping Li           | 1564.1012-000       | 4830             |

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| EXAMINER |
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CHEU, CHANGHWA J

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/724,304

Applicant(s)

LI ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Restriction/Election***

1. Applicant's election on Group I, claims 1-5, 7-11, with traverse is acknowledged. Applicant pointed out that claim 6 which is an *isolated nucleic acid* molecule which encodes the amino acid SEQ ID No. 2, should be included in Group I instead of separating it into Group II. Examiner agrees and thus regroups claim 6 in Group I.
2. However, after review the grouping of the instant invention. Examiner considers that claim 7, with a distinct features of "*a portion of SEQ ID No. 1: which is at least about 10 contiguous nucleotides; and a portion of the complement of SEQ ID No. 1: which is at least about 10 contiguous nucleotides, under conditions appropriate for selective hybridization*" can be practiced by a materially different product other than Group I. Therefore, claim 7 is patentably distinct and unrelated from Group I. Thus the instant Group I includes claims 1-6 and 8-12.
3. During a telephone conversation with Ms. Ingrid Beattie on April 4, 2003, an election was made without traverse to prosecute the invention of Group I, claims 1-6, 8-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7, 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. The Restriction Requirement is deemed proper and is therefore made **FINAL**.

**DETAILED ACTION**

***Specification***

5. The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 7, line 4 and 23). Applicant is requested to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01

***Claim Rejections - 35 USC § 101***

***Utility***

6. Claims 1-6, 8-12 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

7. The claimed nucleic acids, i.e. SEQ ID No. 1 and No. 2, are not supported by a specific asserted utility because the disclosed uses of the nucleic acids or encoded proteins are not specific and are generally applicable to any nucleic acid and/or proteins. The specification states that the data demonstrates an intended use for tissue marker, i.e. osteoblast. (See Figure 2; Specification page 2, line 5-14) The specification asserts that "OBP1 provides a marker for osteoblasts, and *may* also have an important regulatory function... thus altering OBP1 expression and /or activity *may* alter the process of in bone formation. Accordingly, OBP1 *may* provide new diagnostic and therapeutic approaches to diseases involving altered bone resorption, such as osteoporosis and periodontal diseases." Supra. The evidence does not support that the instant invention indeed involving the established bone resorption process, bone formation regulation or any specific bone-related disease. These are non-specific uses that are applicable to nucleic acids and/ or proteins in general and not particular or specific to the nucleic acids and/or protein being claimed.

8. Furthermore, the claimed nucleic acids and/or proteins are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid could be used to detect a protein. The protein could then be used in conducting research to functionally characterize the protein, e.g. its possible role in bone formation. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this instant case, none of the SEQ ID No. 1 and No. 2 that are to be produced as final products resulting from processes involving claimed nucleic acids have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Note that "Congress intended that no

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patent be granted on a chemical compound whose sole “utility” consists of its potential role as an object of use-testing”, and stated, in context of the utility requirement, that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966)

9. According to the Federal Guidelines (Fed. Reg. Vol. 66, No. 4, January 5, 2001), an isolated and purified nucleic acid molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. However, based on the disclosure it cannot be predicted that the isolated nucleic acid actually encodes a functional protein, nor does the specification or any art of record teach a relationship to any specific disease or establish any involvement of the invention in the etiology of any specific disease. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polypeptide and fragments thereof. Because the claimed invention is not supported by a specific and substantial utility for the reasons set forth, credibility of any utility cannot be assessed.

#### ***Enablement***

10. Claims 1-6, 8-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reason set forth above, one skill in the art would not know how to use the claimed invention.

#### ***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 5, “which hybridizes under high stringency conditions” is vague and indefinite. It is unclear what sets forth the criteria for “high” stringency conditions in the instant application.

With respect to claim 10, it directs a method but lacks the necessary active steps to carry out the purported purpose. For instance, how does one skill in the art obtain the polypeptides in interest.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 8-12 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bonaldo et al. (Genome Research (1996) 6: 791-806; GenCore version search report)

14. Bonaldo et al. teach normalization and subtraction approaches to facilitate gene discovery. (See Abstract) Bonaldo et al. teach a nucleic acid comprising the instant invention sequence from 319-555 of SEQ ID No. 1 and its corresponding encoded amino acid sequence as SEQ ID No. 2. (See GenCore version) Bonaldo et al. teach hybridization to select nucleic acid complementary to the probes, linked the target sequence with a regulatory sequence, transfecting the interested DNA into host cell, e.g. E. Coli bacteria, and culturing the bacteria for harvesting the polypeptide encoded by the transfected DNA, isolating and identifying the polypeptides from the bacteria. (See Methods: Construction of directionally cDNA libraries, Production of purified covalently closed single-stranded library DNA in vivo, Normalization and Subtraction- page 801-805)

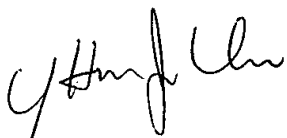
*Conclusion*

15. No claim is allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

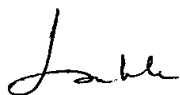
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu  
Examiner  
Art Unit 1641



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May 2, 2003



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05/02/03